

InTec PRODUCTS, INC. (XIAMEN)

(HIV 1&2) Urine Test (Colloidal Gold) Clinical Test Scheme (Plan)

The test is a specially designed clinical test to detect HIV antibodies in human urine. The tests should be carried out in provincial blood bank , HIV hospitals, AIDS Controlling and Protection Center and other prominent Reference laboratories with clinical evaluation capacity, good testing methods. A final evaluation report will be provided.

Clinical Test Scheme: 3 parts

Part I: Sensitivity testing:

Objective: to examine the sensitivity of the rapid test card for the detection of HIV antibodies in human urine.

Method: Collect urine and blood samples from HIV patients. The blood samples should be tested with current testing method such as ELISA. Test the urine samples with the test card. The blood samples should be collected from patients at different stages or from HIV infected people who are infected at different time.

Requirement: Due to lacking of positive and negative controls or references, all positive samples should be collected from patients who are infected at different time or at different stages.

Part II: Random samples testing

Aim: to examine the performance of the test card when testing random samples.

Method: Collect blood and urine samples from healthy people or other non-HIV infected people. The blood samples should be tested with current testing method, such as ELISA.. Test the urine samples with the test card.

Requirement: All samples are considered as non-HIV infected during collection without excluding the possibilities of being infected, such samples may be at the stage of low antibody concentration. Therefore, for the samples, which do not comply to test results, an imported test reagent for blood detection or WB method should be tested. ?? Due to lacking of more accurate test method for urine detection, confirmatory test on urine samples is not recommended. .

Part III: Interfering testing

Aim: to examine the specificity of the test card.

Method: Collect urine and blood samples from HAV, HBV, syphilis, HIV infected persons

respectively. . The blood samples should be tested with HIV antibodies detection reagents. Test the urine samples with the test card. Compare the results to find any relevant factors.

Interfering diseases: hepatitis (HAV, HBV), syphilis and diseases that have similar symptoms to HIV infected people, or other diseases that doctors think need to be checked for HIV antibodies.

Control reagents/methods: Control reagents should be the products, which have a registration number or an import registration number (in case it is imported). The control method should be the recognized testing method at present. Due to lacking of better testing methods and reagents for reference, we employ testing methods and reagents for blood detection as reference. Confirmatory reagents should not be used as control reagents.

Clinical sample collection: 1000 random samples from regular physical examination or HIV antibody negatives, 200 HIV positive samples are tested in clinical evaluation. Specificity testing is conducted in general by using the 1000 random samples/HIV negatives. The Positive samples are tested in epidemic prevention stations and HIV hospitals. Interfering disease examinations are mainly carried out in infection clinics, dermatology and venereal disease clinics and special disease clinics.

Specific test requirement:

1. Urine sample should be tested with the test card, and blood samples be tested with the control reagents/methods. All the original data and records generated from the testing should be kept.
2. The testing results of Rapid Test card should be demonstrated in -, +/-, +, ++, and +++. Number the samples. The testing results of EIA based on the reports are provided by EIA multilevel counters.
3. Original data of the control reagents, and number the samples are required. .
4. Number the samples and perform the test according to the instructions and testing report sheets.
5. Retain the original test data or the test records, number the samples, and send all the data to R&D in InTec PRODUCTS, INC. (XIAMEN).
6. A final testing report on the testing results shall be presented to R&D in InTec PRODUCTS, INC. (XIAMEN).

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(HIV 1/2) Urine Test (Colloidal Gold)

Clinical Test Summary

Based on the Clinical Test Scheme for (HIV 1&2) for the Detection of HIV Antibodies in Human Urine (Colloidal Gold), we take specific measures to carry out the clinical test scheme as following

- 1、 HIV Diagnostic Center of Shanxi Province: 34 samples(both blood and urine) are collected from HIV infected people or Aids patients who have been confirmed by the center 50 samples (blood and urine) from healthy people (anti-HIV negative) and 2 negative samples(blood and urine) Totaling 86 samples. ELISA reagents, Organon Teknika, Boxtel, NL are used as controls; WB reagents by GENELABS in Singapore are used as confirmatory reagents for blood specimens testing. Following table shows that the conformity of positive is 97.06%, negative 96%, total 96.43%.

	Test cards			Total	
	(+)	(±)	(-)		
Control reagents	(+)	33	0	1	34
	(±)	0	0	2	2
	(-)	2	0	48	50
Total	35	0	51	86	

Conclusion: The HIV urine test is easy to operate., no equipment is required. , Therefore it is suitable to be popularized in remote hospitals or clinics. To have a complete clinical data and more accurate testing results, it's recommended that more samples are tested at a time..

- 2、 Beijing Ditan Hospital: 100 AIDS antibody positive blood/urine samples and 300 AIDS antibody negative blood/urine samples are collected. . ELISA reagents by Beijing Wantai are used as controls. Test result shows that the conformity of negative is 100%, positive is 91%, out of which, 5 samples are found to be weak positive and confirmed positive after repeated testing. ; 3 failed but were confirmed positive after retesting for twice.

Test cards

Total

		(+)	(-)	
Control	(+)	91	9	100
Reagents	(-)	0	300	300
Total		91	309	400

Conclusion: The test kit is of good specificity and sensitivity. and almost all the test results consist with the HIV(1&2) EIA reagents.

3、No. 3 People's Hospital of Kunming: 60 samples in total, 30 of the samples are confirmed as HIV infected. Compared to the clinical test of the blood samples, the conformity is 100%.

		Test cards		Total
		(+)	(-)	
Control	(+)	30	0	30
Reagents	(-)	0	30	30
Total		30	30	60

4、No. 3 People's Hospital of Chendu: 1000 urine as well as blood specimens were collected from healthy people. The specificity is 99.2%. Out of the 1000 urine samples, 10 do not conform to blood sample testing results. After retesting with a third party's reagents, 2 negative results given by test cards conform to the confirmatory reagent, 8 not. Both the control reagents and the confirmatory reagents give 8 negative results, 2 false positive results.)

		Test cards		Total
		(+)	(-)	
Control	(+)	0	2	2
reagents	(-)	8	990	998
Total		8	992	1000

Confirmatory testing results

		Test cards		Total	Control reagents		Total
		(+)	(-)		(+)	(-)	
Reassuring	(+)	0	0	0	0	0	0
reagents	(-)	8	2	10	2	8	10
Total		8	2	10	2	8	10

The original data show that the false positive of urine samples and the false positive of blood samples are not from the same source.

5、 Summary

The test results provided by the clinical examination units, 2 urine samples' counterpart blood samples are indefinite; therefore the total amount of tested samples in the HIV Diagnostic Center of Shanxi Province is 84. Other tested samples are counted as they are. Moreover, all HIV antibody positives are confirmed positive by WB blood test, so concluding from the true positive cases, the overall test result is as the following:

		Test card (InTec)		Total
		(+)	(-)	
Control	(+)	154	12	166
reagents	(-)	10	1370	1380
Total		164	1382	1564

Conformity of the positive samples= $154/166=92.8\%$

Conformity of the negative samples= $1370/1380=99.3\%$

Total Conformity= $(154+1370) /1564=97.4\%$

The two indefinite blood samples in the HIV Diagnostic Center of Shanxi Province give negative result in urine test.

According to the clinical examinations, the test cards have good specificity. The sensitivity meets the requirements for preliminary screening. Having been evaluated by clinical labs, the products are considered as a convenient test, which gives visible result.

No clear interference was found in the samples collected from the HBV patients and TP patients in Beijing Ditan Hospital and No. 3 People's Hospital of Kunming.

Enclosure: detail reports from the clinical examination units

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March, 2003